## TENNESSEE BOARD OF PHARMACY SEPTEMBER 21 – 22, 2004 ROOM 160 – DAVY CROCKETT TOWER NASHVILLE, TN

#### **BOARD MEMBERS PRESENT:**

#### STAFF PRESENT:

Robert Shutt, President Reggie Dilliard, Vice President Julie Frazier, Member Sheila Mitchell, Member James R. Mitchell, Member Forrest Parmley, Member Kendall Lynch, Director
Alison Zane, Legal Counsel
Martha Agee, Board Administrator
Terrence Cannada, Pharmacist Investigator
Harry Fuqua, Pharmacist Investigator
Terry Grinder, Pharmacist Investigator
Richard Hadden, Pharmacist Investigator
Ralph Staton, Pharmacist Investigator

The Tennessee Board of Pharmacy convened on Tuesday, September 21, 2004, in Room 160 of the Davy Crockett Tower, 500 James Robertson Parkway, Nashville, Tennessee. A quorum of the members being present, the meeting was called to order at 9:00 a.m. CDT by Dr. Robert Shutt, President. Dr. Shutt noted for the record Mrs. Monica Franklin will not be attending the meeting.

#### **RULEMAKING HEARING**

Mrs. Alison Cleaves, chief legal counsel for the Division of Regulatory Boards, called the rulemaking hearing to order. Mrs. Cleaves introduced Dr. Kendall Lynch, who is the Director for the Tennessee Board of Pharmacy. Mrs. Cleaves stated the rulemaking hearing notice was published in the June 15, 2004, Volume 30, Number 6, of the Tennessee Administrative Register. Mrs. Cleaves stated pursuant to Tennessee Code Annotated §63-10-504 (b) (1), the hearing is being conducted to consider the promulgation of amendments to rules and new rules; and in a manner prescribed by the Uniform Administrative Procedures Acts, T.C.A. §4-5-204, in Room 160 of the Davy Crockett Tower, 500 James Robertson Parkway, Nashville, Tennessee at 9:00 a.m. on the 21<sup>st</sup> day of September, 2004. Mrs. Cleaves explained the rules process to the attendees. After the board adopts the rules, they are forwarded to the Attorney General's office for constitutionality. Mrs. Cleaves asked Dr. Kendall Lynch if notice was given and Dr. Lynch replied "yes". Dr. Lynch stated comments were received from Dr. Kevin Nicholson, Director of Pharmacy Regulatory Affairs, National Association of Chain Drug Stores by letter dated September 16, 2004; Dr. Dan F. Luce, Manager of Patient Care Services, Walgreen Company by e-mail correspondence; and Dr. James Krahulec, Vice President of Government and Trade Relations, Rite

Aid Corporation by letter dated September 20, 2004.Dr. Kevin Nicholson requested clarification of Rules 1140-

1-.01 (6) and 1140-3-.16 (1) (a) relevant to the term "licensed in" to mean "licensed by" as a pharmacy

engaging in centralized prescription processing does not have to be physically located in Tennessee.

Dr. Sheila Mitchell motioned to change the language to read "licensed by"; seconded by Dr. Julie

Frazier. All were in favor and the motion carried.

Dr. Nicholson noted concern to Rule 1140-1.05 (3) relative to the Board allowing NABP to establish the

licensing requirements for foreign pharmacy graduates. The Board reviewed Dr. Nicholson's comment and

stated no change was necessary as the language is currently contained in Rule 1140-1-.05 (4).Dr. Dan Luce

recommended in the new proposed section, Rule 1140-3-.16 - Automated Dispensing of Devises for Pharmacy

Practice under Centralized Prescription Processing - Rule 1140-3-.16 (2) (b) which states, "the maintenance of

records to identify the responsible pharmacist(s) in the dispensing and counseling processes", to remove the

language "and counseling" and change the word processes.

Dr. Robert Mitchell motioned to remove the words "and counseling" in the dispensing "process";

seconded by Dr. Sheila Mitchell. All were in favor and the motion carried.

Dr. Dan Luce noted concern under proposed Rule 1140-3-.16 (2) (b) relevant to there being no requirement to

record the pharmacist responsible for counseling. The Board reviewed Dr. Luce's comment and stated no

change was necessary as the word "pharmacies" was probably mistaken to be "pharmacists". Dr. James

Krahulec submitted comments and requested clarification of the language under Rules 1140-1-.01 (6) and

1140-3-.16 (1) (a), to change "licensed in" to read "licensed by". Dr. Krahulec commented on the language in

proposed Rule 1140-3-.16 (2) (d) which states, "The pharmacies that are not physically located in the State of

Tennessee shall comply with Tenn. Code Ann. Title 63, Chapter 10 and the rules of the State of Tennessee

Board of Pharmacy" seems to indicate that a pharmacy does not need to be physically located in Tennessee.

The Board noted Tennessee Code Annotated §63-10-410 permits the licensing of out-of-state pharmacies. Dr.

Krahulec commented on proposed Rule 1140-1-.05 (3) relevant to "...and any other requirements established

by the NABP". Rite Aid expressed concern that the Board may be engaging in improper rulemaking as the

September 21 – 22, 2004

future requirements imposed by NABP must be subject to the proper rulemaking procedures of public notice and comment. The Board stated no change was necessary as this language is currently contained in Rule 1140-1-.05 (4).

#### **RULE 1140-1-.01 DEFINITIONS.**

(6) "Centralized Prescription Processing" ...one (1) pharmacy licensed by the State of Tennessee..."

#### **RULE 1140-1-.05 LICENSING EXAMINATIONS.**

(1) "... An applicant shall also meet the minimum acceptable passing scores on the NAPLEX and MPJE that are set by the NABP.

Dr. Sheila Mitchell motioned to place a period after MPJE; seconded by Dr. Robert Mitchell. Dr. Robert Mitchell withdrew his second. The motion did not carry.

Dr. Julie Frazier motioned, "An applicant shall also meet the acceptable passing scores on the NAPLEX and MPJE as established and nationally accepted." Dr. Sheila Mitchell seconded the motion. All were in favor and the motion carried.

#### **RULE 1140-3-.15 REFERENCE BOOKS.**

A suggestion to amend the existing rule and replace with the new proposed rule language to state: "Each pharmacy practice site **may** maintain an adequate reference..." "The reference library **shall** include a current edition of the Tennessee Pharmacy Laws ..."

## RULE 1140-3-.16 AUTOMATED DISPENSING DEVISES FOR PHARMACY PRACTICE. CENTRALIZED PRESCRIPTION PROCESSING:

- (1) A pharmacy...
  - a. both pharmacies shall be licensed by the State of Tennessee; and
- (2) The pharmacy...
  - a. the maintenance of records to identify the responsible pharmacist(s) in the dispensing process.

## **RULE 1140-6-.03 LIBRARY.**

A suggestion to amend the existing rule and replace with the new proposed rule language to state: Each nuclear pharmacy practice site <u>shall</u> maintain an adequate reference library... Dr. Sheila Mitchell motioned to change the word "shall" to "may", seconded by Dr. Julie Frazier. All were in favor and the motion carried.

Dr. Robert Mitchell motioned **to accept all the rules**; seconded by Dr. Julie Frazier. All were in favor and the motion carried. Chief legal counsel, Mrs. Cleaves, asked for a Roll Call Vote.

ROLL CALL VOTE
Aye

There were six (6) Ayes, zero (0) Nays. The motion carried.

#### APPROVAL OF THE MINUTES

The **minutes of the July 14 - 15, 2004,** board meeting were presented and reviewed by the Board. Dr. Julie Frazier motioned **to approve** the minutes; seconded by Dr. Forrest Parmley. All were in favor and the motion carried.

## AMY VOORHEES – REQUEST FOR REINSTATEMENT OF LICENSE HERMITAGE, TN

Dr. Amy Voorhees appeared before the Board to request the reinstatement of her pharmacist license. Dr. Kim Roberts, Dr. Tina Posey and Dr. Morris Haddox with TPRN advocated on her behalf. Director Kendall Lynch advised on July 20, 2003, the office received a telephone call from Dr. Voorhees employer's loss prevention stating she was dispensing unauthorized prescriptions for herself. In April, 2004, Dr. Voorhees was discharged from Cornerstone and was in the process of obtaining advocacy. Dr. Voorhees stated she entered Cresthaven in Memphis, Tennessee in August, 2003 for approximately two (2) months and was discharged and entered Cornerstone in Knoxville. In January, 2004, Dr. Voorhees was briefly discharged due to a violation of the rules, but completed treatment and obtained advocacy. Dr. Morris Haddox, advocate with TPRN, stated Dr. Voorhees was compliant with the recommendations of TPRN. Dr. Kim Roberts and Dr. Tina Posey with TPRN stated they support Dr. Voorhees' return to the practice of pharmacy. Dr. Voorhees stated she has been working as a technician with CVS since June, 2004. Dr. Jay Dickerson, pharmacy supervisor with CVS, stated to the Board that Dr. Voorhees has supportive sponsors, attends meetings daily, demonstrates Professionalism, and works well with coworkers. After board discussion, Dr. Sheila Mitchell motioned to:

- Respondent does hereby agree to the reinstatement of license number <u>12236</u> with the following probationary conditions. Said probation shall remain in effect for a period of five (5) years, from <u>September 21, 2004 to September 21, 2009</u>.
  - a. The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b).
  - b. The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, <u>Paul Turpin</u>, <u>MD</u>, except in the case of an emergency or upon a proper referral from the Respondent's primary physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;
  - c. The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devises containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;
  - d. The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;
  - e. The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
  - f. The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacists Recovery Network for as long as the Respondent has

an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;

- g. the Respondent shall comply with all of the terms and conditions of the extended aftercare contract he or she entered into with Tennessee Pharmacists Recovery Network. Respondent shall return a copy of said contract with this Consent Order to the Board office;
- h. the Respondent shall not serve as pharmacist-in-charge for a period of three (3) years, however, after a period of two (2) years, the Respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon a show of good cause. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without the permission of the Board;
- i. If the license has been inactive, delinquent, suspended or revoked:
  - i. Less than one (1) year, the pharmacist shall:
    - 1. Provide written notice requesting an active license;
    - 2. Satisfy all past due continuing pharmaceutical education; and
    - 3. Pay all cumulative license renewal fees and any applicable penalties.

Dr. Julie Frazier seconded the motion. All were in favor and the motion carried. Dr. Robert Shutt, President of the Board, encouraged Dr. Voorhees to "stay with the family".

## AMY VOORHEES - REQUEST FOR EXCEPTION TO THE CONSENT ORDER FOR REINSTATEMENT

Dr. Amy Voorhees contacted Director Kendall Lynch after appearing before the Board relevant to the terms outlined in Section "h" of the Consent Order whereas it states, "The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without the permission of the Board." Dr. Voorhees is requesting an exception to the Consent Order for Reinstatement she entered into with the Board's permission to work no more than forty (40) hours at CVS Pharmacy in Gallatin and a CVS Pharmacy in Hendersonville. Dr. Sheila Mitchell motioned **to approve the exception**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

## RASHUNDA SCOTT, RT – REQUEST FOR APPROVAL OF TECHNICIAN REGISTRATION JACKSON, TN

Ms. Rashunda Scott appeared before the Board to request the approval of her technician registration. Dr. Kendall Lynch stated on June 5, 2003 Ms. Scott submitted an application for a technician registration In September, 2003, Ms. Scott was employed with Family Meds in Jackson, Tennessee and she provided a written statement to Loss Prevention stating, "I took two (2) bottles of 500 count Hydrocodone 7.5/500 for my own use without making payments. I wish to keep my job and step down from checking in the order with the supervision of my manager." Dr. Lynch stated the office mailed a letter dated October 22, 2003, denying the application based on the information furnished by her employer and offered her the opportunity to appear before the Board. In May, 2004, the office received another application from Jackson Clinic Pharmacy and Ms. Scott was notified of the denial on June 22, 2004 and she was advised the application would be presented to the Board for consideration. On July 16, 2004, a letter advising Ms. Scott of the board's decision to deny the application was mailed. The members stated a personal appearance would be required should Ms. Scott dispute their decision and allowed thirty (30) days to provide notice to appeal pursuant to the terms of the Tennessee Uniform Administrative Procedures Acts. Mrs. Alison Cleaves, legal counsel, advised pursuant to T.C.A. §63-10-505 (6) Unprofessional Conduct, the Board has the authority to deny the application. Ms. Scott advised she is a single parent with two children and receives no child support. Ms. Scott humbly regrets the decision she made on that day as she enjoys working as a technician and assisting the customers. Since May, 2004, Ms. Scott stated she has been unable to work as a technician as she could not obtain a registration. Ms.

Scott stated she has never had a drug or alcohol problem but sold the Hydrocodone to provide support for her children. Ms. Scott stated she has made restitution to her employer. The Board inquired if letters of recommendation were submitted on Ms. Scott's behalf and Dr. Lynch replied there was no record of letters of recommendation from previous employers. Ms. Scott stated she received the Pharmacy Technician Certification in October, 1999 and the children's father is gainfully employed and able to provide child support. The Board requested either a letter of recommendation be provided or an advocate to also appear. Dr. Kendall Lynch advised Ms. Scott was not informed of the Board's requests. Dr. Robert Shutt requested some type of statement from the PIC regarding this instance. Dr. Sheila Mitchell motioned to deny the request for approval of the registration application; seconded by Dr. Robert Mitchell. All were in favor and the motion carried. Dr. Robert Mitchell advised an advocate should appear with you. Dr. Kendall Lynch provided Ms. Scott with some guidelines.

## DIRECTOR/BOARD MEMBER MEETING WITH COMMISSIONER PAULA FLOWERS – AUGUST 30, 2004

Director Kendall Lynch and board member, Dr. Julie Frazier met with Commissioner Paula Flowers, et. al., on Monday, August 30, 2004, at the Davy Crockett Tower, 500 James Robertson Parkway, Nashville, Tennessee, to discuss the board member's authority and responsibility, the role and considerations of legal counsel; administrative considerations; and departmental legislation.

#### **BOARD MEMBER AUTHORITY AND RESPONSIBILITY**

#### Chairperson's Role

- The Chair is encouraged and should vote on all issues.
- The Chair is encouraged to participate in the preparation of the meeting agenda.

#### Robert's Rules of Order

• In accordance with Commissioner Flowers meeting, Director Kendall Lynch discussed with the board members to consider adopting the Robert's Rules of Order for the purpose of board minutes. For example: if one member disagrees with the motion, it would be recorded in the minutes as six (6) Ayes, one (1) Nay. The only time a member's vote will be identified is with a Roll Call Vote.

#### **POLICY STATEMENT**

### **ROBERT'S RULES OF ORDER**

All meetings of the Tennessee Board of Pharmacy are conducted in accordance with the latest revision of *Robert's Rules of Order,* except where such rules are contrary to any provisions of laws and rules of the Tennessee Board of Pharmacy. In such situations, the provisions of the laws and rules shall prevail. (September 21-22, 2004).

Robert E. Shutt, President Tennessee Board of Pharmacy

Kendall M. Lynch, Director

Dr. Robert Mitchell motioned **to accept the policy statement for Robert's Rules of Order**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### **LEGAL CONSIDERATIONS**

### **Open Meetings**

- Adequate notice of meetings: Seven (7) days.
- Adequate listing of agenda items: Agendas should provide adequate information about what topics are to be discussed or heard.
- Teleconferences: All meetings held via a telephone conference can only be done out of necessity.
- Polling of Board Members: No Ex Parte communication is allowed by a board member.

#### Minutes vs. transcription of meetings and proceedings

 The General Counsel for Commerce and Insurance supports retaining a court reporter for meetings due to the inconsistency of the minutes. It was mentioned to state your name for clarity.

#### Public Record

• Board minutes, inspections and investigational documents are public records. Work products that are furnished to the board's legal counsel are not for public view.

### Interpretation of Laws, Policies and Rulemaking

 Board members are encouraged to look for defensible language such as the word "shall". The word "may" does not convey a particular authority.

### <u>Ultra Vires Actions – No Representation by the Attorney General</u>

 If a board member is investigated or charged criminally, you cannot be represented by the Attorney General.

• If a board member is named in a civil matter, the Attorney General can represent the individual or make arrangements for outside counsel.

#### Internal Investigations

• If a board member requests an investigation, it should be referred to either the board staff or legal counsel. If the investigation involves a staff member, it should be referred to either legal counsel or the Attorney General's Office.

#### Administrative Considerations

 All staff members of a board are employees of the Department of Commerce and Insurance. The Director and Pharmacist Investigators for the Board of Pharmacy are an exception.

## **Legislation**

 The departmental legislative package which has not been finalized may include fee increases, an upgrade of the RBS computer system and a provision for electronic license renewal.

#### Conflict of Interest Disclosure Statements

• Dr. Julie Frazier and Dr. Reggie Dilliard expressed concern with the Conflict of Interest Statement relevant to the section stating, "While serving on any board or commission, the board or commission member shall not serve as an officer, or otherwise serve in a policy-making role, in any trade or professional association." It is permissible to serve on these committees or professional associations provided the member does not participate in considerations or actions concerning the Board of which he/she is a member.

MALTAGON OCTOBER 17 – 20, 2004 NEW ORLEANS, LA

Director Kendall Lynch advised the members there would be no reimbursement for attending MALTAGON this year.

## CHARLES LAFEVOR, DPH – FORMAL HEARING HARRIMAN. TN

Dr. Charles LaFevor appeared for a Formal Hearing before the Board to consider the revocation of his pharmacist license for diversion and refilling prescriptions without authorization. Mrs. Alison Cleaves, Chief Legal Counsel represented the Department of Commerce and Insurance for the "State of Tennessee". The Honorable James Hornsby, Administrative Law Judge with the Secretary of State's Office, presided at the hearing and requested the board to state their name for the record. In attendance were Dr. Robert Shutt, Dr.

September 21 – 22, 2004

Reggie Dilliard, Dr. Julie Frazier, Dr. Sheila Mitchell, Dr. Robert Mitchell, and Dr. Forrest Parmley. Mrs. Monica

Franklin was not present.

FINDING OF THE FACTS:

Dr. Sheila Mitchell motioned to accept the Allegations of Fact in the Notice of Hearing and Charges as

stated; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

**CONCLUSION OF LAW:** 

Dr. Reggie Dilliard motioned to accept the Notice of Hearing and Charges as stated outlining each

violation of the laws and rules as the Conclusion of Law; seconded by Dr. Julie Frazier. All were in favor

and the motion carried.

**POLICY STATEMENT:** 

Dr. Reggie Dilliard motioned the Board has determined a violation of pharmacy law and by doing so adopt the

Board's vested power and authority, seconded by Dr. Julie Frazier. All were in favor and the motion carried. Dr.

Reggie Dilliard motioned to revoke License #724; seconded by Dr. Julie Frazier. All were in favor and the

motion carried.

A copy of the court reporter's summary is attached and will become an official document to the minutes.

**CONSENT ORDERS** 

LAURA JO BARBER, DPH 1935 St. Gregory Court

Knoxville, TN 37931

Mrs. Alison Cleaves, chief legal counsel, presented a Consent Order, whereas in 2001 and 2002 Dr. Laura

Barber was in violation of T.C.A. §53-10-105 (a) relevant to the forging of three (3) prescriptions for

Cephalexin. Dr. Barber was assessed a civil penalty of \$1,000. Dr. Julie Frazier motioned to accept the

Consent Order; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

Tennessee Board of Pharmacy September 21 – 22, 2004 CHARLES JEFFREY CHRISTIAN, DPH 4162 Skyland Drive Kingsport, TN 37664

Chief legal counsel, Mrs. Alison Cleaves, presented a Consent Order for Reinstatement of License for Dr. Charles Christian. Dr. Christian's license has a probationary term of ten (10) years from May 25, 2004 – May 25, 2014 and must notify all future employers of his Health and Human Services (HHS) exclusion. Dr. Julie Frazier motioned to **accept the Consent Order for Reinstatement**; seconded by Dr. Sheila Mitchell. All were in favor and the motion carried.

GREGORY KIRK JONES, DPH 434 Coral Wood Drive Kingsport, TN 37663

A Consent Order for the Reinstatement of License for Dr. Gregory Jones was presented by Mrs. Alison Cleaves, chief legal counsel for Regulatory Boards. Dr. Jones' term of probation is for ten (10) years from July 14, 2004 – July 14, 2014. Dr. Robert Mitchell motioned to accept the Consent Order for Reinstatement of License; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

BEN C. LOTT, DPH 5917 Westmere Drive Knoxville, TN 37909

Mrs. Alison Cleaves, legal counsel, presented a Consent Order whereas Dr. Ben Lott was in violation of Rule 1140-2-.01 (11) (a) relevant to the substitution of Ampicillin 500 mg. with Amoxicillin 500 mg. without authorization from the physician. Dr. Lott was assessed a \$250 civil penalty. Dr. Reggie Dilliard motioned to accept the Consent Order; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

THOMAS R. RICHARDSON, DPH 22 Harper Cove Jackson, TN 38305

A Consent Order for Revocation of Dr. Thomas Richardson's license was presented to the Board by Mrs. Alison Cleaves, counsel. Dr. Richardson violated the terms of his Consent Order on March 24, 2004 by consuming Adderall and forging prescriptions for himself. Dr. Julie Frazier motioned to **accept the Consent Order for Revocation**; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

Tennessee Board of Pharmacy September 21 – 22, 2004 JEFFREY ALESSIO, DPH 150 Paradise Drive Hendersonville, TN 37075

Mrs. Alison Cleaves, chief legal counsel, presented a Consent Order whereas Dr. Jeffrey Alessio was in violation of Rule 1140-2-.01 (1), relevant to misfilling a prescription for liquid Zantac with liquid Zyrtec for a three (3) month old child, who consumed the medication. Dr. Alessio was assessed a civil penalty of \$500 and indicated by note that he had completed a two (2) hour course in September 2004 entitled, "CVS/Pharmacy Quality First - Misfill Prescriptions" as instructed by the board and a copy of the completed course will be furnished upon receipt. Dr. Robert Mitchell motioned to **accept the Consent Order**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

LEONARD HUGH PARTON, DPH 5871 McMinnville Highway Woodbury, TN 37190

Chief legal counsel, Mrs. Alison Cleaves, presented a Consent Order for the indefinite suspension of Dr. Leonard Parton's license whereas Dr. Parton admitted being chemical dependent. Dr. Julie Frazier motioned to accept the Consent Order; seconded by Dr. Sheila Mitchell. All were in favor and the motion carried.

#### **DIRECTOR'S REPORT**

# NATIONAL ASSOCIATION OF BOARDS OF PHARMACY NAPLEX BLUEPRINT AND NEW PASSING STANDARD

Director Kendall Lynch stated the National Association of Boards of Pharmacy has announced that it has concluded a recent analysis of the practice of pharmacy. The analysis consists of an evaluation of current educational outcomes and competency statements and an expert review of the current NAPLEX blueprint content. As a result of the analysis, revisions were made to the current NAPLEX blueprint, which include increasing the emphasis on communication skills, treating over-the-counter and prescription products equally and adding a competency addressing dietary supplements. The new passing standard will go into effect in May, 2005, and the minimum passing score remains a scaled score of 75. The NAPLEX Competency Statements will consists of Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes

September 21 – 22, 2004

(54% of test); Assure Safe and Accurate Preparation and Dispensing of Medications (35% of test); and Provide

Health Care Information and Promote Public Health (11% of test).

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY NOMINATIONS FOR EXECUTIVE COMMITTEE REPRESENTING DISTRICT III

Director Kendall Lynch advised the Board that Dr. Reggie Dilliard is a candidate for the District III Executive

Committee as Dr. Michael Moné's term will expire at the NABP's 2005 Annual Meeting.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY **FSMB EDUCATIONAL WORKSHOP SERIES** 

Director Kendall Lynch advised the Federation of State Medical Boards is offering a series of workshops

relevant to "Promoting Balance and Consistency in the Regulatory Oversight of Pain Care". State boards may

designate up to two (2) representatives to receive scholarships to cover the expenses for attending one of the

workshops.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY FALL CONFERENCE

**NOVEMBER 11 – 14. 2004** ST. PETERSBURG, FL

Director Kendall Lynch stated an out-of-state travel request would be submitted for the Director and one (1)

board member to attend the NABP's Fall Conference on November 11 – 14, 2004 in St. Petersburg, Florida.

Dr. Robert Shutt was selected by the members to attend.

2005 DISTRICT III MEETING

**AUGUST 7 – 9, 2005** 

KNOXVILLE, TN

The Tennessee Board of Pharmacy will host the 2005 District III Meeting to be held at the Marriott Hotel in

Knoxville, Tennessee on August 7 – 9, 2005. Director Lynch requested an appointment for a steering

committee to be established. Dr Julie Frazier and Dr. Reggie Dilliard were selected.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY TEST OF ENGLISH AS A FOREIGN LANGUAGE (TOEFL)

Director Kendall Lynch advised the members that the National Association of Boards of Pharmacy will be

administering a new form of the Test of English as a Foreign Language (TOEFL) in September 2005. The test

September 21 – 22, 2004

will consist of four (4) sections: reading, writing, listening, and speaking. The new TOEFL will no longer require

the Test of Spoken English (TSE) as the new TOEFL will have a speaking component. The board's present

Rule 1140-1-.05 (4) will need to be amended.

TRIPARTITE MEETING

OCTOBER 21 – 22, 2004

NASHVILLE, TN

The Tennessee Pharmacist Association will host the Tripartite Meeting to be held on October 21 – 22, 2004 at

the Embassy Suite Airport in Nashville, Tennessee.

**GOVERNOR'S TASK FORCE ON METHAMPHETAMINE ABUSE** 

Director Kendall Lynch reported to the Board some of the recommendations suggested by the Governor's Task

Force relevant to the abuse of Methamphetamine. The task force advised the State should require that all

products that contain pseudoephedrine or ephedrine be sold only behind the counter in licensed pharmacies.

The purchasers of viable products should be required to present identification at the point of sale and

pharmacists should be required to maintain a record of the sale. The State should impose limits making it

unlawful to sell or possess more than three (3) packets of any product containing pseudoephedrine or

ephedrine, or quantities of more than nine grams. The State should implement an administrative system to

determine when and if additional products should be subject to restrictions.

**WAIVERS** 

JOYCE R. BROWN, DPH

TAYLOR BROWN APOTHECARY

3349 Maple Hollow Cove

Southaven, MS 38672-7500

Dr. Joyce Brown is requesting a waiver of Rule 1140-3-.14 (12) relevant to the pharmacist-in-charge at more

than (1) pharmacy practice site. Dr. Brown is currently the PIC at Taylor Brown Apothecary and is requesting to

be PIC at Apothecary Compounding Laboratory, a compounding pharmacy. Dr. Julie Frazier motioned to

**approve the waiver**; seconded by Dr. Reggie Dilliard.

All were in favor and the motion carried.

Tennessee Board of Pharmacy September 21 – 22, 2004 WILLIAM C. CROWDER, DPH C & M PHARMACY P.O. Box 486 Lawrenceburg, TN 38464

Dr. William Crowder is requesting a waiver of Rule 1140-1-.07 (3) (c) (3) relevant to the requirement for the successful completion of the NAPLEX examination. Dr. Crowder's license has been in "invalid" status since October 31, 1993 and he did not receive the letter relevant to the rule changes in 1998. Dr. Crowder is not practicing, but is willing to do the CE's and has paid all delinquent licensing fees. Dr. Crowder stated the current PIC at C & M Pharmacy is planning to retire. Dr. Sheila Mitchell motioned to **grant the waiver request**; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

MICHAEL DECHRISTOFARO, DPH 22 Gislornes Circle Crossville, TN 38555

Dr. Michael DeChristofaro is requesting to have the PIC privileges reinstated pursuant to the terms of the Consent Order for Reinstatement he entered into with the Board in July, 2002. The Order stated Dr. DeChristofaro may petition the Board to allow him to be the PIC after two (2) years. Advocate Dr. Larry Branstetter advised TPRN supports the change. Dr. Robert Mitchell motioned to **approve the Modification to the Consent Order**; seconded by Dr. Sheila Mitchell.

All were in favor and the motion carried.

BRAD HOPKINS, DPH AMPHARM, INC. P. O. Box 307 Parsons, TN 38363

Dr. Brad Hopkins is requesting a waiver of Rule 1140-3-.14 (12) relevant to the pharmacist in charge at more than one (1) pharmacy practice site. Dr. Hopkins is currently the PIC at Ampharm Pharmacy, a long term care facility. AmMed Home Care Pharmacy is a mail order pharmacy that services thirty (30) to forty (40) prescriptions per day. Both of the pharmacies are located in the same building. Dr. Hopkins is also requesting a waiver of Rule 1140-1-.12 (e) relevant to the hot and cold running water for AmMed Home Care Pharmacy. The sink is approximately eighteen (18) feet from Ampharm Pharmacy. Dr. Sheila Mitchell motioned to approve both of the waiver requests; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

September 21 – 22, 2004

**BRENDA MCINTYRE, DPH** 

P. O. Box 4340

Brookings, OR 97415

Dr. Brenda McIntyre is requesting a waiver of Rule 1140-1-.07 (3) (c) (3) relevant to the successful completion

of the NAPLEX exam. Dr. McIntyre's license expired on May 31, 1998 and she did not receive the Board's

letter regarding the rule changes in 1998. Dr. Julie Frazier motioned to grant the wavier; seconded by Dr.

Reggie Dilliard.

All were in favor and the motion carried.

LARRY H. MILLS, DPH

P.O. Box 1014

Lexington, TN 38351

Dr. Larry Mills is requesting a waiver of Rule 1140-5-.01 relevant to the Live ACPE continuing education

requirements for the renewal of his license due to a medical hardship. Dr. Julie Frazier motioned to allow Dr.

Mills a six (6) month extension in which to obtain thirty (30) hours of ACPE continuing education and

to waive the Live for this renewal cycle only. The CE's will not count towards the next renewal. Dr.

Reggie Dilliard seconded the motion.

All were in favor and the motion carried.

PATSY SIMS, DPH

P. O. Box 697

**Sparta, TN 38583** 

Dr. Patsy Sims is requesting a waiver of Rule 1140-1-.07 (3) (c) (3) relevant to the successful completion of the

NAPLEX exam. In January, 1999, the Board received a response to the 1998 rule letter indicating she was

aware of the rule change requirement. Dr. Sheila Mitchell motioned to deny the request; seconded by Dr.

Julie Frazier. Dr. Robert Mitchell abstained.

The motion carried.

**VALERIE SMITH, DPH** 

54 W. Mirror Ridge Circle

The Woodlands, TX 77382

Dr. Valerie Smith is requesting a waiver of Rule 1140-5-.01 relevant to the Live ACPE continuing education

requirement for the renewal of her pharmacist license. Dr. Smith is employed with McKesson Medication

Management and was required to complete a thirty (30) course from McKesson's Pharmacy Practice

Standards Training Program. The program did not consist of any live hours. Dr. Sheila Mitchell motioned to

grant Dr. Smith a six (6) month extension to obtain the Live hours; seconded by Dr. Robert Mitchell.

All were in favor and the motion carried.

JAGDEEPAKPAL THIND, DPH 10-710 Spring Gardens Road **Burlington, ONTARIO** 

L7T 4K7

CANADA

Dr. Jagdeepakpal Thind is requesting a waiver of Rule 1140-5-.01 relevant to the Live ACPE continuing

education requirement for the renewal of his pharmacist license. In May, 2002, the Board granted Dr. Thind a

similar waiver request. Dr. Sheila Mitchell motioned to **deny the request**; seconded by Dr. Forrest Parmley.

All were in favor and the motion carried.

**WAYNE SHAFER. DPH** CONTRACT PHARMACY SERVICES, INC.

122 North York Road #4 Hatboro, PA 19040

Dr. Wayne Shafer is requesting a waiver of Rule 1140-1-.07 (3) (c) (3) relevant to the requirement for the

successful completion of the NAPLEX and the Tennessee Jurisprudence Exam to reinstate his pharmacist

license. Dr. Shafer's license was in an expired status and he did not receive the Board's letter regarding the

rule changes in 1998. Dr. Sheila Mitchell motioned to waive the NAPLEX only; seconded by Dr. Robert

Mitchell.

All were in favor and the motion carried.

September 21 – 22, 2004

TENNESSEE DEPARTMENT OF HEALTH

**NATIONAL IMMUNIZATION PROGRAM** 

Director Kendall Lynch stated he had received inquiries from pharmacists in regards to their participation in the

National Immunization Program. The program is approved for four and one-half (4 ½) continuing education

hours for nurses. The Board requested Dr. Lynch to review the contents of the agenda to determine it's

relevance to the practice of pharmacy. Dr. Julie Frazier motioned to allow the Executive Director to approve

as non-ACPE; seconded by Dr. Robert Mitchell.

All were in favor and the motion carried.

**ADJOURNMENT** 

Dr. Robert Shutt entertained for a motion to adjourn. Dr. Julie Frazier motioned to adjourn the meeting on

Tuesday, September 21, 2004 at 4:25 p.m. CDT. All were in favor and the motion carried.

**RECONVENED** 

The Board of Pharmacy reconvened on Wednesday, September 22, 2004 at 9:00 a.m. CDT in Room 160 of

the Davy Crockett Tower. President Robert Shutt called the meeting to order. All members were present with

the exception of Mrs. Monica Franklin. Director Kendall Lynch introduced Ms. Ashley Vance, a 4th year UT

pharmacy student, who is completing her rotations at Southern Hills Hospital.

LEGAL REPORT/COMPLAINTS

1. Case No.: L04-PHR-RBS-200317238

The Complainant alleges that the Respondent purposely delayed filing his prescriptions on two (2) occasions, damaged his vehicle with the drive-thru window and almost caught the Complainant's hand in the drive-thru window bin. The Complainant further alleges that the Respondent was unprofessional, rude and combative and that the Respondent did not give the Complainant a seventy-two (72) hour supply of

Toprol XL which is mandated by TennCare.

prescriptions and states that insurance approval delayed delivery on both occasions. The Respondent denies purposefully closing the Complainant's hand in the drive-thru bin. Respondent states that he began to pull the bin inwards when he realized that the Complainant did not retrieve all of his prescriptions from the bin. The Respondent apologized to the Complainant. The Respondent denies damaging the Complainant's vehicle with the drive-thru window. In terms of the seventy-two (72) hour supply, it appears that the Complainant was upset because he was made to wait in the drive-thru because there were some

The Respondent denies the allegation that he purposely delayed delivery of the Complainant's

insurance problems with two (2) of his prescriptions. The Complainant then entered the store, very agitated, and the Respondent states that he did not even have an opportunity to inform him about a three

(3) day supply because the Complainant left the store.

Previous complaints: DPh: None

Pharmacy: None

**Recommendation: Dismiss** 

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 2. Case No.: L04-PHR-RBS-200418807

The complaint alleges that the Respondent, a registered technician, falsified her technician application. The Respondent responded "no" to the question on the application stating, "Have you ever been convicted of a felony?" The Respondent later admitted to us that in 1985, she was charged with the misapplication of funds while employed at a bank. The Respondent received a sentence and a term of probation both of which were completed by the Respondent. The Respondent was also fined fifty dollars (\$50.00) and paid restitution. The Respondent claims that she was advised by a co-worker that she did not need to disclose the felony conviction. The Respondent would not state the name of that pharmacist. It should also be noted that the Respondent brought this to our attention upon the advice of her counsel.

### **Recommendation: Letter of Warning**

Dr. Reggie Dilliard motioned to **accept counsel's recommendation**; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

#### 3. Case No.: L04-PHR-RBS-200419312

The complaint alleges that the Respondent was terminated from his employment as a pharmacist for dispensing Z-Pak and Lisinopril without a prescription.

The Respondent admits to the following:

- (1) That he dispensed Z-Pak to his son's girlfriend without a prescription (he subsequently obtained the prescription from the physician):
- (2) That he gave himself a few refills for Toprol and Generic Silvadene Cream when the doctor was not available:
- (3) That he took four (4) tablets of Generic Motrin without paying for it (he had a prescription for the Motrin);
- (4) That he dispensed Z-Pak and Lisinopril for his son who had prescriptions for these medications at another pharmacy.

There was also some concern about the Respondent's prescription for Hydrocodone APAP 5/500 that was called into the pharmacy, but our investigator verified that the prescription was authorized. A technician has also seen the Respondent take a Lortab and a Donnatal off of the shelf and also asked the technician to dispense Lortab to him without a prescription. Another technician stated that she has seen the Respondent write out a prescription for Mobic 7.5mg for his wife.

Previous complaints: None

Recommendation: Consent Order for Probation for one (1) year with usual terms and conditions with an additional provision that the Respondent shall not fill any prescriptions for himself or his family members.

Dr. Forrest Parmley motioned to accept counsel's recommendation; seconded by Dr. Reggie Dilliard. Dr. Julie Frazier, Dr. Sheila Mitchell and Dr. Robert Mitchell voted "no". The motion failed.

Dr. Sheila Mitchell motioned to issue a Consent Order with a civil penalty for \$500; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

#### 4. Case No.: L04-PHR-RBS-200419338

The Complainant alleges that when the pharmacy dispensed her prescription for Humira, which requires refrigeration, the Respondent found the prescription in the "will call" bin. The Complainant brought the medication home and contacted her physician who indicated to her that the medication should be destroyed. The Complainant brought the medication back to the pharmacy and marked it with a red "D" and the pharmacy replaced the medication. The Complainant then returned to the pharmacy one (1) month later to fill her prescription for Humira and they gave her the same package and she returned one (1) month earlier with a red "D" on it. The pharmacy once again, replaced the medication.

The Respondent, pharmacy states that the Humira was retained by the pharmacy and not destroyed when it was brought back by the Complainant because the pharmacy determined that the medication was in a unit dose, unopened commercially pre-packaged container that met the federal and state standards for product integrity. Two issues: Should the pharmacist have kept the medication refrigerated and out of the "will call" bin?, Should the pharmacist have destroyed the medication once it was brought back by the Complainant?

Previous complaints: DPh: None

Pharmacy: None

Recommendation: Discretion of the Board

Dr. Sheila Mitchell motioned to issue a Consent Order with a civil penalty of \$250 to the pharmacist for re-dispensing; a \$250 civil penalty to the pharmacy; and a Letter of Warning to the pharmacist in charge. Dr. Forrest Parmley seconded the motion. All were in favor and the motion carried.

#### 5. Case No.: L04-PHR-RBS-200419446

The complaint alleges that the Respondent, a registered pharmacy technician diverted controlled substances from the pharmacy where she was employed. On May 26, 2004, the pharmacy manager observed the Respondent placing two (2) bottles in her smock. As the Respondent exited the pharmacy, the pharmacist searched her pockets and found 1 x 100 Xanax 1 mg and 1 x 100 Lortab 10mg. An audit conducted on June 2, 2004 revealed the following shortages:  $50 \times 100 \text{ Lortab } 10$ ,  $5 \times 100 \text{ Lortab } 7.5 \text{ and } 3 \times 100 \text{ Xanax } 1 \text{ mg}$ .

## Recommendation: Formal Hearing (Consent Order for Revocation/Surrender)

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 6. Case No.: L04-PHR-RBS-200418492

The complaint alleges that the Respondent misfilled a prescription for Amoxicillin 400mg/5ml with Clavulinic Acid generic for Amoxil 400/5. The patient consumed the medication and experienced nausea and began vomiting necessitating an emergency room visit. The pharmacist states that the prescription was entered correctly into the computer, but that the error was made when the technician mistakenly pulled the wrong medication off of the shelf. As a result of this incident, the pharmacy has imposed more stringent check procedures in place as well as installing a ScriptPro unit.

Previous complaints: DPh: None

Pharmacy: None

**Recommendation: Letter of Warning** 

Dr. Forrest Parmley motioned to **accept counsel's recommendation**; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

#### 7. Case No.: L04-PHR-RBS-200419442

The Complainant alleges that the pharmacy (pharmacy A) was unable to supply her with her medication promptly on several occasions and she was forced to wait for five (5) to seven (7) days for her pain medication. Complainant also alleges that another pharmacy (pharmacy B) routinely substituted her prescription for Kadian with MSContin

Pharmacy A states that they have been filling the Complainant's prescriptions since June, 2003. The pharmacist admits that there have been some delays in supplying the Complainant's medication, Kadian. The pharmacy inadvertently ordered the wrong strength of the medication resulting in a five (5) to seven (7) day delay. On another occasion, the pharmacy waited for a new prescription in anticipation that the doctor would change to Avinza since Kadian became a prior approval drug on TennCare. A technician who also responded to the complaint, states that the Complainant was made aware "from the beginning" that they would not order the drug until they got a prescription since the dosage may change.

An investigation of Pharmacy B revealed that Pharmacy B filled the Complainant's prescriptions for Kadian and substituted MS Contin for the Kadian because the Complainant told the DPh that her doctor had previously prescribed MS Contin for her. The DPh states that he obtained the physician authorization for one of the substitutions, but then did not obtain the physician's authorization subsequent prescriptions.

Previous complaints: Pharmacy A: None

DPh (DG): None Pharmacy B: None DPh (KD): None

Recommendation: Letter of Warning to DPh for substituting MSContin for Kadian (KD)

Dr. Julie Frazier motioned to accept counsel's recommendation and explain the reason why the Board does not consider this a substitution as he did not contact the doctor and in the event this happens in the future, a civil penalty will be assessed. Dr. Reggie Dilliard seconded the motion. All were in favor and the motion carried.

#### 8. Case No.: L04-PHR-RBS-200419520

There are two (2) complaints under this case number. The first complaint alleges that the pharmacist left the hospital pharmacy for approximately 2 ½ hours leaving a technician alone in the pharmacy. The pharmacist states that she left the pharmacy for approximately 1 ½ hours to give a lecture. The pharmacist scheduled the lecture on that particular day because she usually has another pharmacist scheduled then. When the pharmacist realized that the relief pharmacist would not be in on that day, she contacted her supervisor to decide if she should shut down the pharmacy or not attend the lecture. After speaking to her supervisor, the pharmacist shut down the pharmacy and displayed the sign "Pharmacist not on duty". She then advised her technician to stay on the floor and enter orders at the nursing station and to page her if an emergency should arise.

The other complaint alleges that the pharmacist acted illegally by not checking the accuracy of the amounts of controlled substances being returned by the DEA registered reverse distributor. The Complainant alleges that when the pharmacist was asked to count the controlled substances that were to be destroyed by the DEA representative, she said that she did not have time. So, the representative left without the checking the accuracy of the drug count. I do not believe we received a response to this complaint, but

even if pharmacist admitted to this activity, there is no law or a rule that requires the pharmacist to verify these counts.

Previous complaints: DPh: None

Pharmacy: None

**Recommendation: Dismissal** 

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Forrest Parmley. All were in favor and the motion carried.

#### 9. Case No.: L04-PHR-RBS-200419595

The complaint was generated by a TennCare Program Integrity investigation into forged prescriptions. The investigation revealed the following: Pharmacist JHD mistakenly filled a called-in prescription for Carisoprodol 350 mg, 30 tablets with 120 tablets. Also, pharmacist JHD mistakenly filled a called-in prescription for Hydrocodone/APAP 10/500, 90 tablets, 2 refills by entering 3 refills in the computer, which resulted in the prescription being refilled 3 times. In response, the pharmacist simply addressed the fact that he unwittingly filled a forged prescription. He says that they have since improved their policy about taking prescriptions by phone and voice mail as follows: Only the certified technician can take new prescriptions over the phone that must be initialed by the technician and the pharmacist with the date and time; Only the pharmacist can write up called-in prescriptions for controlled substances with the DEA number, date and time written on the front; all prescriptions left on the answering machine must be saved and verified by the pharmacist.

Pharmacist CSK originally filled a prescription for Hydrocodone APAP 10/500, 90 tablets and then refilled that prescription with 180 tablets. The pharmacist states that the technician entered the refill and filled the prescription not knowing that she was violating federal law. The pharmacist did not check the prescription for quantity, only for proper content and correct patient information.

Previous complaints: DPh (CSK): None

DPh (JHD): None Pharmacy: None

Recommendation: Letters of Warning against both pharmacists. JHD for dispensing the wrong number of refills and CKS for refilling a prescription for a Schedule III controlled substance with an amount that exceeds the original prescription.

Dr. Julie Frazier motioned to **accept counsel's recommendation** to the pharmacist and PIC; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

#### 10. Case No.: L04-PHR-RBS-200419596

The Complainant alleges that the Respondent mistakenly filled her prescription for Claritin with both Claritin and Ambien. The Complainant further alleges that she consumed a single Ambien, which caused her to hallucinate and go to the emergency room for observation and that two (2) weeks after the incident, she is still experiencing headaches and dizziness.

The pharmacist admits that he incorrectly entered the prescription as Ambien 10mg instead of Claritin 10mg; the prescription was difficult to read. The pharmacist also states that the Complainant's husband was counseled about the medication. The pharmacist states that their procedure at pharmacy is to double count any controlled substance prescription. The verifying pharmacist states that in this instance this prescription was counted by two (2) separate people and neither of them noticed that Claritin and Ambien

were in the same bottle. The verifying pharmacist suspects that the contents from the Complainant's old bottle of Claritin were mixed in with the new bottle by the Complainant.

Previous complaints: DPh (JS): None

DPh (DM): None Pharmacy: None

Recommendation: Letter of Warning to JS for the misfill and for failing to contact the physician about verifying the prescription.

Dr. Julie Frazier motioned to **accept counsel's recommendation**; seconded by Dr. Sheila Mitchell. All were in favor and the motion carried.

#### 11. Case No.: L04-PHR-RNS-2004200005

The Complainant alleges that the pharmacy filled a prescription written for a ninety (90) day supply of Rhinocort Aqua only eleven (11) days after the first prescription was filled. The prescription was first filled on July 8, 2004 with a sixty (60) day supply, instead of a ninety (90) day supply. On July 19, 2004, the pharmacy corrected the error and sent the Complainant a ninety (90) day supply, but it arrived eleven (11) days after the first prescription was filled. The Complainant then said that he would not pay for the other script.

The PIC states that on July 5, 2004, he received a prescription for Rhinocort Aqua for the Complainant's wife for one (1) spray in each nostril daily and to dispense a quantity of three (3) inhalers. According to the directions and the patient's insurance, the pharmacy can fill up to a three (3) month supply. Based on the directions on the prescription and the manufacturer's information that each bottle contains 120 sprays, two (2) bottles were dispensed on July 8, 2004, which would have been a three (3) month supply. On July 16, 2004, the Complainant's physician phoned in a new prescription for increasing the directions to two (2) sprays in each nostril and the quantity. Since there was a dosage increase and the previous supply would have been used more quickly, the pharmacy shipped the second prescription with three (3) inhalers. Since the directions were written incorrectly on the first prescription, the pharmacy calculated that the first prescription would only last another 12 to 15 days, so they then decided to fill and ship the full quantity of the second prescription. At the Complainant's request, the pharmacy issued a pick-up order to return the medication, which was destroyed and credited the co-pay.

Previous complaints: DPh: None

Pharmacy: None

**Recommendation: Dismissal** 

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. Dr. Reggie Dilliard stepped out of the room. The motion carried.

#### 12. Case No.: L04-PHR-RBS-200420006

The Complainant alleges that her privacy was violated by the pharmacist who discussed the dosage of her medication (Oxycontin) in a "loud discussion" so that others could hear. The Complainant also alleges that someone at the pharmacy altered her prescriptions for Oxycontin and Norflex, which caused her physician to dismiss her from her pain management program for altering a prescription.

The pharmacist states that she simply asked the Complainant how she was taking the medication and the Complainant "screamed" that her doctor had changed the directions on her Oxycontin prescription from two (2) times a day to three (3) times a day and challenged the pharmacist's authority to ask the question. The

pharmacist then told the Complainant that she would need to check with the physician to confirm the three (3) times a day dosage. The pharmacist was also suspicious that the Complainant's prescription for Orphendrine 100mg had been altered to read two (2) tablets two (2) times a day instead of one (1) tablet two (2) times a day. The pharmacist contacted physician who confirmed that the prescription had been altered.

Previous complaints: DPh: None

Pharmacy: None

**Recommendation: Dismissal** 

Dr. Julie Frazier motioned to **dismiss the complaint**; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

#### 13. Case No.: L04-PHR-RBS-200420092

The complaint was initiated upon referral from the local Sheriff's office and the TBI alleging possible diversion. The patient's husband stated that in the past they have always gotten ninety (90) Hydrocodone with APAP 5/500, but the last time, they only received forty (40) tablets. Our investigation revealed that the original prescription was written for one hundred (100) tablets with three (3) refills for a total quantity of four hundred (400) tablets. The patient's insurance would only pay for ninety (90) tablets at a time. There were forty (40) tablets remaining when the last prescription was refilled. The label on the bottle reflected that amount and the pharmacy records were also correct.

Previous complaints: DPh: None

Pharmacy: None

**Recommendation: Dismissal** 

Dr. Sheila Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 14. Case No.: L04-PHR-RBS-200440102

The complaint alleges that the Respondent admitted that on or about June 1, 2004, he took 1 x 30 Levitra 2.5 mg tablets from the pharmacy where he was employed, which had a value of approximately two hundred and fifty dollars (\$250.00). Two (2) technicians observed the theft and reported it to the pharmacy security. The pharmacist then admitted the theft to security and returned the unopened bottle. The Respondent was then suspended and subsequently terminated from his employment.

Previous complaints: 2002- Agreed Order three year term of probation

#### **Recommendation: Formal Hearing**

Dr. Reggie Dilliard motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 15. Case No.: L04-PHR-RBS-200419738

The complaint alleges that the registered technician was observed on video tape taking 1 x 500 Hydrocodone 7/5/500 on or about May 17, 2004. The Respondent was confronted by the loss prevention coordinator and the Respondent admitted to the 2004 diversion as well as the diversion of approximately 15 x 500 Hydrocodone since December, 2003. The Respondent was terminated and arrested.

## Recommendation: Formal Hearing (Consent Order for Surrender)

Dr. Sheila Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 16. Case No.: L04-PHR-RBS-200419599

The Complainant alleges that her prescription for Humalog Pen 100u/ml was filled with an out-of-date product that was to be used at meals per established sliding scale. The product was dispensed on February 1, 2001, it went out of date on November 1, 2000 and the error was discovered on or about August, 2001. The Complainant further alleges that as a result of taking this out-of-date medication, her diabetes to advanced which caused her to lose her eyesight.

The pharmacist who dispensed the out-of-date medication admits the error. The PIC states that they have a system already in place to prevent this type of error, but it failed in this instance. One of our investigators recently visited the pharmacy in August, 2004 and there were no out-of-date products on the shelves.

Previous complaints: DPh: None

Pharmacy: None

### **Recommendation: Letter of Warning to PIC**

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Sheila Mitchell. All were in favor and the motion carried.

#### 17. Case No.: L04-PIC-RBS-200419852

The complaint alleges that the Respondent has been working as a floater pharmacy with an expired license since June 21, 2004. The pharmacist admits the error, but states that he experienced a house fire in 2003, which destroyed all of his records, upset his routine and as a result, he was unaware of the expiration date of his license. Respondent also states that he did not receive a renewal notice and was not notified that his license had expired. Respondent's license expired on June 30, 2003. Staff's records indicate that they sent the Respondent a notice about his renewal certified mail in October, 2003, but that it was not claimed. Respondent has submitted all of his fees, including late fees and continuing education credits.

Previous complaints: DPh: (1/01, working for three (3) months without a license, \$300.00 civil penalty and must submit an additional 15.5 hours of CE)

#### Recommendation: Consent Order with \$1,100.00 civil penalty

Dr. Sheila Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 18. Case No.: L02-PHR-RBS-200211143

The Complainant, an emergency room nurse, alleges that she observed three (3) prescription bottles from the same pharmacy for Dilantin 100 mg with the following directions:

Prescription number 1 had directions "Take 3 capsules at bedtime."

Prescription number 2 had directions "Take 4 capsulea (sic) at bedtime."

Prescription number 3 had directions "Take 32 capsukes (sic) at bedtime."

The Complainant also alleges that she contacted the pharmacist to confirm the directions, but stated that the pharmacist seemed unsure of the correct dosage.

The pharmacist admits the typographical error and states that he did speak to the nurse and told her that it was a typographical error and told her the correct dosage. The pharmacist also states that he spoke with the patient about the directions and that the patient, who had been taking the medication for approximately ten (10) years, understood the correct dosage.

Previous complaints: DPh: (1/97, lack of patient counseling, \$100.00 civil penalty)

Pharmacy: (1/97, lack of patient counseling, \$500.00 civil penalty)

Recommendation: Letter of Warning about improper directions

Dr. Julie Frazier motioned to **accept counsel's recommendation**; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

#### 19. Case No.: L04-PHR-RBS-200419504

The complaint was initiated after receiving two (2) anonymous emails alleging that the Respondent pharmacy routinely violates the pharmacist to pharmacy technician ratio and that the pharmacy allows the pharmacy technicians to provide patient counseling. An investigator visited the pharmacy on July 1, 2004. At that time, the investigator observed that the pharmacy was in compliance with the pharmacist/ technician ratio. The investigator presented the pharmacy with a new prescription for Penicillin VK 500 mg. The investigator was handed a profile sheet to complete since he had never been to the pharmacy before and was asked if he had any medication allergies. Before the investigator completed the questionnaire, the cashier told him that the prescription was ready; he then paid for the medication and no counseling was provided or offered. The investigator then went back into the pharmacy and notified the DPh of the violation and reviewed the relevant rule him.

The DPh, PIC and technician all submitted the same response, which states that they are sorry about the report and that "the service was available, but not used." The response also states that since the investigator's visit, they have implemented a new system to prevent future errors. Prior to the investigator's visit, the pharmacists were only providing patient counseling to those patients who had concerns or problems with their medication. Now, the pharmacy is providing/ offering patient counseling in accordance with the Board's rule.

Previous complaints: DPh (PIC): None

DPh (MBA): None Pharmacy: None

Recommendation: Consent Order with a \$100.00 civil penalty to the DPh and a \$500.00 civil penalty to the pharmacy for lack of patient counseling.

Dr. Reggie Dilliard motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

#### 20. Case No.: L04-PHR-RBS-200419609

The complaint alleges that the Respondent pharmacist was terminated from the pharmacy where he was employed because of theft. The Respondent admitted to taking merchandise from the store and paid for it at a later time. The Respondent also admitted he would fail to charge the retail price for some medications when the patient was on a fixed income or for himself, his family and/or friends. The Respondent admitted that there were other times when he would deliver medications to his patients or family and then receive full

September 21 – 22, 2004

payment at a later date. The Respondent reported this incident to the Board office and stated that money difficulties is the reason for this behavior and that he will be reimbursing his employer, attending employee assistance and consumer debt counseling.

Previous complaints: DPh: None

Recommendation: Consent Order placing Respondent on one (1) year of probation with the following terms: Respondent cannot fill his own prescriptions or prescriptions for family members, Respondent must keep us informed of his place of employment and Respondent must inform the PIC of each pharmacy where he is employed that he is on probation with the Board

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

#### 21. Case No.: L04-PHR-RBS-200420297

The complaint alleges that the Respondent, unlicensed online Canadian pharmacy has dispensed controlled substances to a Tennessee resident. The medications obtained were 120 x Alprazolam 1 mg and 4 x Tadalafil 20 mg. The medication was not accompanied by any dispensing label containing directions, physician's name, pharmacy name, directions for use or date of dispensing. Also, the medication was not dispensed through a storefront in Tennessee. All attempts to locate an address for the Respondent were unsuccessful.

Recommendation: Investigation with the Food and Drug Administration

Legal counsel, Mrs. Alison Cleaves did not present the complaint to the Board.

#### 22. Case No.: L04-PHR-RBS-200420545

The complaint alleges that the Respondent, while on probation with the Board, tested positive for Fentanyl on April 29, 2004. Other urine screens were collected at various times before and after April 29<sup>th</sup> and all of those screens were negative. The Respondent denies taking the Fentanyl. On or about September 17, 2004, we received a phone call from the Respondent's TPRN advocate stating that the Respondent had relapsed on alcohol and that the Respondent had admitted this conduct.

Previous complaints: 1992- CO for Suspension

1997- Reinstatement 1998- CO for Surrender

2003- Reinstatement with 10 year term of probation with the Board

Recommendation: Formal Hearing (Consent Order for Revocation and cannot reapply for 5 years).

Dr. Robert Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

\*\*Dr. Sheila Mitchell questioned if the pharmacist confessed he violated the Consent Order, why would the Board send a Consent Order for Revocation of License when the pharmacist admitted addiction? Legal counsel, Mrs. Cleaves, stated the recommendation refers to an "and/or" authority granted by the board, in which if the pharmacist did not sign the Consent Order for Revocation, it would allow counsel to proceed with a Formal Hearing.

Dr. Sheila Mitchell motioned to **accept the terminology**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

23. Case No.: L03-PHR-RBS-200316366

The complaint alleges that the Respondent was convicted of three (3) counts of insurance fraud. The Respondent fraudulently dispensed and billed drugs for his wife without the authorization of a physician. On March 15, 2003, the Respondent entered into a Memorandum of Understanding ("MOU") in Circuit Court that suspends prosecution of the case for a period of one (1) year subject to certain conditions.

The Board previously authorized a Consent Order for a three (3) year term of probation with the usual terms and conditions with a provision directing the Respondent to comply with the MOU and not to fill any prescriptions for himself or his family members. The Respondent's attorney contacted me shortly after receiving this Consent Order and indicated that his client would sign the Consent Order without the PIC restriction since the Respondent operates a small pharmacy without another pharmacist who could take over the PIC position.

Recommendation: Consent Order with a three (3) year term of probation containing the usual terms and conditions and directing the Respondent to comply with the provisions of the MOU and that the Respondent shall not fill any prescriptions for himself or his family members with the exception of the PIC requirement.

Dr. Sheila Mitchell motioned to **accept counsel's recommendation**; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

#### 24. Case No.: L99-PHR-RBS-199900022

The complaint alleged that the pharmacy had a loss of approximately 36,000 solid oral dosage units of Hydrocodone products among three (3) pharmacies. A complaint was established against one (1) of the pharmacists who worked at all three (3) pharmacies. Although there was no evidence that this pharmacist was responsible for the Hydrocodone loss, the pharmacist did admit to taking three (3) Effexor tablets and three (3) Trazadone tablets from the pharmacy which resulted in a Letter of Warning. At that time, the Board requested that a representative from the pharmacy appear at its next meeting. At that next meeting (January 20, 2004), the Board asked the pharmacy to report back to us within six (6) months about their efforts in controlled this theft. The pharmacy reported to the Board office that they traced the losses to a courier who serviced all three (3) pharmacies.

#### **Recommendation: Closure**

Dr. Reggie Dilliard motioned to **accept counsel's recommendation**; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

## JENNIFER SPIVEY, DPH MCKENZIE, TN

Legal counsel, Mrs. Alison Cleaves, advised the Board that a Consent Order for Reinstatement of License for Dr. Jennifer Spivey was approved at the July 14 – 15, 2004 meeting. The Consent Order stated an incorrect probationary term for ten (10) years, which should state a term of probation for five (5) years. Mrs. Cleaves stated she would initial the Consent Order for Reinstatement and change the term to reflect <u>May 25, 2004 – May 25, 2009</u> and forward a corrected copy to Dr. Spivey. The board approved of the change.

President Robert Shutt discussed with the board members the job performance of the director and

investigators. Dr. Shutt stated pursuant to Tennessee Code Annotated §63-10-503 (b), grants the Board the

authority to recommend an increase in the salaries and requested a salary survey be conducted from other

state boards of pharmacy. Dr. Sheila Mitchell motioned, at the discretion of the President of the Tennessee

Board of Pharmacy, Director Kendall Lynch and I will perform a salary survey to reflect comparable market

salaries and present at the November 16 - 17, 2004 board meeting. Dr. Robert Mitchell seconded the motion.

All were in favor and the motion carried.

ADJOURNMENT FOR LUNCH

President Robert Shutt stated the Board will adjourn for lunch at 11:40 on Wednesday, September 22, 2004

and will reconvene at 3:00 for scheduled Formal Hearings.

**RECONVENED** 

The Board of Pharmacy reconvened on Wednesday, September 22, 2004 at 3:00 p.m. CDT in Room 160 of

the Davy Crockett Tower. President Robert Shutt called the meeting to order. All members were present with

the exception of Mrs. Monica Franklin.

LAURA WILSON, RT - FORMAL HEARING

#200418571

13325 Stukee Creek Drive

Philadelphia, TN 37846

At approximately 3:05 p.m. CDT, Mrs. Alison Cleaves noted to the Honorable James Hornsby to begin with the

Formal Hearing as Ms. Laura Wilson was not present nor represented by legal counsel. Mrs. Alison Cleaves,

chief legal counsel for the Department of Commerce and Insurance represented the "State of Tennessee". The

Honorable James Hornsby, Administrative Law Judge with the Secretary of State's Office presided at the

hearing and requested the board to state their name for the record. In attendance were Dr. Robert Shutt, Dr.

Reggie Dilliard, Dr. Julie Frazier, Dr. Sheila Mitchell, Dr. Robert Mitchell, Dr. Forrest Parmley, Witness #1 Dr.

Kendall Lynch and Witness #2 Mr. Chris Howard. The witnesses were sworn in by Judge Hornsby. Mrs. Alison

September 21 – 22, 2004

Cleaves advised Judge Hornsby that proper notice had been given pursuant to the Sunshine Law and requested to proceed with the hearing with a Motion to Default.

Dr. Reggie Dilliard motioned to accept the Motion to Default; seconded by Dr. Robert Mitchell. All were in favor and the motion carried. The Motion for Default was granted by Administrative Law Judge James Hornsby. Director Kendall Lynch stated Ms. Wilson was first licensed as a registered pharmacy technician on August 15, 2003 and is currently registered. Mr. Chris Howard, loss prevention for Rite Aid #1352 Corporation in East Tennessee, whose duties are to protect the company's assets and recover assets from employee pilferaging. On March 25, 2003, an investigation was initiated due to a complaint received and cameras were installed in the pharmacy. An audit revealed a loss of Hydrocodone. Ms. Wilson was observed removing sixteen (16) tablets of Hydrocodone and placing them in another bottle, then placed the tablets in her front pocket. On April 2, 2003 Officer Bill Evans with the Loudon police department was notified to meet with Rite Aid Loss Prevention. Ms. Wilson was shown the tape and asked if she wanted to make any statement, verbal and/or written. Officer Joni Crisp stated in the arrest report, "On April 2, 2003, Sergeant Bridges received a call from Chris Howard, an investigator from Rite Aid on Highway 72 in Loudon. Mr. Howard suspected Ms. Wilson of taking pills from the pharmacy. The investigator interviewed Ms. Wilson and she admitted to taking 50 – 60 Hydrocodone 10/500 and 10 Hydrocodone 10/325 over the past two (2) weeks. The loss was reported on the DEA/106 form. Ms. Wilson had no prescriptions for Hydrocodone. Mrs. Alison Cleaves stated the "State" requests the revocation of Ms. Wilson's pharmacy technician registration. Administrative Law Judge Hornsby advised the board members they would need to vote on #1. The Finding of Facts; #2 Conclusion of Law; and #3 Policy Statement. Dr. Reggie Dilliard motioned to adopt the Notice of Hearing and Charges as the Board's Finding of Facts; seconded by Dr. Robert Mitchell. All were in favor and the motion carried.

Dr. Sheila Mitchell motioned to accept the Conclusion of Law as stated in the Notice of Hearing and Charges; seconded by Dr. Julie Frazier. All were in favor and the motion carried. Dr. Reggie Dilliard motioned, it is the policy of this board to discipline the license or registration holder under T.C.A. §63-10-505 (a) and in doing so should discipline in this matter as well as revoke the registration of Laura M. Wilson #13761; seconded by Dr. Julie Frazier. All were in favor and the motion carried.

A copy of the court reporter's summary is attached and will become an official document to the minutes.

## **ADJOURNMENT**

Dr. Sheila Mitchell motioned to adjourn the board meeti	ng on Wednesday, September 22, 2004 at 3:36 p.m
---	---

CDT; seconded by Dr. Reggie Dilliard. All were in favor and the motion carried.

Respectfully submitted,
Robert Shutt, President
Kendall M. Lynch, Director